

CLAIMS

1. A chemical complex comprising:
 - i) a beta-2 adrenoceptor agonist; and
 - 5 ii) an aminosugar.
2. A chemical complex according to claim 1, wherein the beta-2 adrenoceptor agonist is selected from the group consisting of bambuterol, bitolterol, broxaterol, carbuterol, clenbuterol, clorprenaline, dioxethedrine, dopexamine, ephedrine, epinephrine, etafedrine,
10 ethylnorepinephrine, fenoterol, formoterol, hexoprenaline, isoetarine, isoproterenol, mabuterol, metaproterenol, methoxyphenamine orciprenaline, pirbuterol, procaterol, protokylol, reproterol, rimiterol, ritodrine, salbutamol (albuterol), salmeterol, soterenol, terbutaline, tretoquinol, tulobuterol, derivatives and salts thereof.
- 15 3. The chemical complex according to any one of claims 1 or 2, wherein said aminosugar is an aminosugar derivative selected from the group consisting of an aminosugar derivative of a monosaccharide, aminosugar derivative of a di or oligosaccharide, aminosugar derivative of a polysaccharide, derivatives and salts thereof.
- 20 4. The chemical complex according to claim 3, wherein said aminosugar derivative has a molecular weight of less than 5000 Daltons, preferably less than 4000 Daltons, more preferably less than 3000 Daltons.
5. The chemical complex according to any one of claims 1 or 2, wherein said aminosugar is
25 an aminosugar derivative of a monosaccharide selected from the group consisting of glucosamine, galactosamine, mannosamine, derivatives and salts thereof.
6. The chemical complex according to any one of claims 2 or 3, wherein said aminosugar derivative comprises a saccharide selected from the group consisting of glucosamine,
30 galactosamine and mannosamine.
7. The chemical complex according to any one of preceding claims, wherein said aminosugar is N-acetylated.
- 35 8. The chemical complex according to any one of preceding claims, wherein said aminosugar is a sulfate salt or a hydrochloride salt.

9. The chemical complex according to any one of preceding claims, wherein the aminosugar is a glucosamine sulfate.

10. The chemical complex according to any one of preceding claims, wherein the beta-2
5 adrenoceptor agonist and the aminosugar are present in a molar ratio of between about 1:10000 to 10000:1, preferably about 1:1000 to 1000:1, such as about 1:100 to 100:1, such as about 1:10 to 10:1, also about 1:5 to 5:1, such as about 1:2 to 2:1.

11. A composition comprising:

- 10 i) a beta-2 adrenoceptor agonist;
ii) an aminosugar; and optionally
iii) one or more acceptable excipients or carriers.

12. The composition according to claim 11, wherein the beta-2 adrenoceptor agonist is
15 selected from the group consisting of bambuterol, bitolterol, carbuterol, clenbuterol, clorprenaline, dioxethedrine, dopexamine, ephedrine, epinephrine, etafedrine, ethylnorepinephrine, fenoterol, formoterol, hexoprenaline, isoetarine, isoproterenol, mabuterol, metaproterenol, methoxyphenamine, pirbuterol, procaterol, protokylol, reproterol, rimiterol, ritodrine, salbutamol (albuterol), salmeterol, soterenol, terbutaline,
20 tretoquinol, tulobuterol, derivatives and salts thereof.

13. The composition according to any one of claims 11 or 12, wherein said aminosugar is an aminosugar derivative selected from the group consisting of an aminosugar derivative of a monosaccharide, aminosugar derivative of a di or oligosaccharide, aminosugar
25 derivative of a polysaccharide, derivatives and salts thereof.

14. The composition according to claim 13, wherein said aminosugar derivative has a molecular weight of less than 5000 Daltons, preferably less than 4000 Daltons, more preferably less than 3000 Daltons.

30

15. The composition according to any one of claims 11 or 12, wherein said aminosugar is an aminosugar derivative of a monosaccharide selected from the group consisting of glucosamine, galactosamine, mannosamine, derivatives and salts thereof.

35 16. The composition according to any one of claims 12 or 13, wherein said aminosugar derivative comprises a saccharide selected from the group consisting of glucosamine, galactosamine and mannosamine.

17. The composition according to any one of claims 11 to 16, wherein said aminosugar is N-acetylated.
18. The composition according to any one of claims 11 to 17, wherein said aminosugar is a sulfate salt or a hydrochloride salt.
19. The composition according to one of claims 11 to 18, wherein the aminosugar is a glucosamine sulfate.
20. The composition according to any one of claims 11 to 19, wherein the beta-2 adrenoceptor agonist and the aminosugar are present in a molar ratio of between about 1:10000 to 10000:1, preferably about 1:1000 to 1000:1, such as about 1:100 to 100:1, such as about 1:10 to 10:1, also about 1:5 to 5:1, such as about 1:2 to 2:1.
21. The composition according to claim 11, comprising a complex comprising the beta-2 adrenoceptor agonist and the aminosugar.
22. The composition according to any one of claims 8 to 13 further comprising one or more therapeutically active agents other than a beta-2 adrenoceptor agonist and the aminosugar.
23. The composition according to any one of claims 8 to 14 in a form selected from the group consisting of oral formulation, topical formulation, transdermal formulation, and parenteral formulation.
24. Use of a combination of a beta-2 adrenoceptor agonist and an aminosugar for the preparation of a medicament for the immunomodulation of a mammal, such as a human.
25. The use according to claim 24, wherein the immunomodulation is treatment of hypersensitivity and/or inflammatory reactions.
26. The use according to claim 25, wherein the immunomodulation is associated with diseases and disorders selected from the group consisting of hypersensitivity skin disease, atopic eczema, contact dermatitis, seborrhoeic eczema, psoriasis, IgE mediated allergic reactions, asthma, allergic rhinitis, anaphylaxis, autoimmune disease, chronic inflammatory disease, Crohn's disease, ulcerative colitis, rheumatoid arthritis, gout, osteoarthritis, pain and cancer.

27. The use according to any one of claims 24 to 26, wherein the medicament comprises a composition as defined by any one of claims 11 to 22.

28. The use according to any one of claims 24 to 26, wherein the medicament comprises a
5 chemical complex as defined in any one of claims 1 to 10.

29. The use according to any one of claims 24 to 28, wherein the beta-2 adrenoceptor agonist and the aminosugar are together comprised in a single formulation or are each individually comprised in separate formulations.

10

30. The use according to any one of claims 24 to 29, wherein the medicament is in a form selected from the group consisting of oral formulation, topical formulation, transdermal formulation, and parenteral formulation.

15 31. The use according any one of claims 24 to 30, wherein the medicament further comprises one or more therapeutically active agents.

32. A method for immunomodulation in a mammal, such as a human, comprising the administration to said mammal of a combination of a beta-2 adrenoceptor agonist and an
20 aminosugar, or pharmaceutically acceptable salts thereof,
or a chemical complex comprising a beta-2 adrenoceptor agonist and an aminosugar, or pharmaceutically acceptable salts thereof.

33. The method according to claim 28 for the suppression of hypersensitivity and/or
25 inflammatory reaction in a mammal, such as a human, comprising the administration of a combination of a beta-2 adrenoceptor agonist and an aminosugar, or pharmaceutically acceptable salts thereof, or a chemical complex comprising said combination or said salts to said mammal.

30 34. The method according to claim 32 for the treatment or prevention of hypersensitivity skin disease in a mammal, such as a human, comprising the administration of a combination of a beta-2 adrenoceptor agonist and an aminosugar, or pharmaceutically acceptable salts thereof, or a chemical complex comprising said combination or said salts to said mammal.

35

35. The method according to claim 32 for the treatment or prevention of atopic eczema, contact dermatitis, seborrhoeic eczema and/or psoriasis in a mammal, such as a human, comprising the administration of a combination of a beta-2 adrenoceptor agonist and an

aminosugar, or pharmaceutically acceptable salts thereof, or a chemical complex comprising said combination or said salts to said mammal.

36. The method according to claim 32 for the treatment or prevention of IgE mediated
5 allergic reaction and/or condition in a mammal, such as a human, comprising the administration of a combination of a beta-2 adrenoceptor agonist and an aminosugar, or pharmaceutically acceptable salts thereof, or a chemical complex comprising said combination or said salts to said mammal.

10 37. The method according to claim 32 for the treatment or prevention of asthma, allergic rhinitis, and/or anaphylaxis in a mammal, such as a human, comprising the administration of a combination of a beta-2 adrenoceptor agonist and an aminosugar, or pharmaceutically acceptable salts thereof, or a chemical complex comprising said combination or said salts to said mammal.

15 38. The method according to claim 32 for the treatment or prevention of autoimmune disease and/or chronic inflammatory disease in a mammal, such as a human, comprising the administration of a combination of a beta-2 adrenoceptor agonist and an aminosugar, or pharmaceutically acceptable salts thereof, or a chemical complex comprising said
20 combination or said salts to said mammal.

39. The method according to claim 32 for the treatment or prevention of diabetes, Crohn's disease, ulcerative colitis, rheumatoid arthritis, gout or osteoarthritis in a mammal, such as a human, comprising the administration of a combination of a beta-2 adrenoceptor
25 agonist and an aminosugar, or pharmaceutically acceptable salts thereof, or a chemical complex comprising said combination or said salts to said mammal.

40. The method according to claim 32 for the alleviation of pain in a mammal, such as a human, comprising the administration of a combination of a beta-2 adrenoceptor agonist
30 and an aminosugar, or pharmaceutically acceptable salts thereof, or a chemical complex comprising said combination or said salts to said mammal.

41. The method according to claim 32 for the treatment or prevention of cancer in a mammal, such as a human, comprising the administration of a combination of a beta-2
35 adrenoceptor agonist and an aminosugar, or pharmaceutically acceptable salts thereof, or a chemical complex comprising said combination or said salts to said mammal.

42. The method according to claim 32, wherein the combination of a beta-2 adrenoceptor agonist and an aminosugar is a chemical complex as defined in claims 1 to 10.

43. The method according to claim 32, wherein the combination of a beta-2 adrenoceptor agonist and an aminosugar is a composition as defined in any one of claims 11 to 23.

5 44. The method according to claims 32, wherein the combination of a beta-2 adrenoceptor agonist and an aminosugar, or pharmaceutically acceptable salts thereof, are together comprised in a single formulation or are each individually comprised in separate formulations.

10 45. The method according to claim 32, wherein the combination of a beta-2 adrenoceptor agonist and an aminosugar is administered by means of oral, topical, transdermal, or parenteral administration, or combinations thereof.

46. The method according to claim 39, wherein the separate formulations are administered
15 in a simultaneous or non-simultaneous manner.

47. The method according to claim 46, wherein the separate formulations further comprises one or more therapeutically active substances.

20 48. The method according to any one of claim 44, wherein the combination of a beta-2 adrenoceptor agonist and an aminosugar are together comprised in a single formulation.

49. The method according to claim 48, wherein the single formulation further comprises one or more therapeutically active substances.

25

50. A process for the preparation of a complex comprising i) a beta-2 adrenoceptor agonist; and ii) an aminosugar, comprising the steps of:

i) dissolving said beta-2 adrenoceptor and said aminosugar in a volatile solvent or a mixture of volatile solvents; and

30 ii) removing said suitable solvent so as to obtain a moisture content of at the most 5% w/w.

51. The process according to claim 50, wherein the volatile solvent is selected from the group consisting of water, water-miscible volatile organic solvents and mixtures thereof.

35

52. The process according to any one of claims 50 or 51, wherein the solvent is removed by spray drying or freeze-drying.

53. The process according to to any one of claims 50 to 52 , wherein the moisture content is at the most 3% w/w, preferably at the most about 2% w/w, more preferably at the most about 1% w/w, even more preferably at the most about 0.5 % w/w, most preferably at the most about 0.2 % w/w.